

Application No.: 09/738,810
Amendment Dated: August 4, 2004
Reply to Advisory Action Dated: July 26, 2004

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

Claim 1. (Previously presented): A powder or granule composition consisting of:

- (a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof, and
- (b) a binder consisting of about 0.1 to about 10% by weight of pectin, calculated based on the total weight of the composition thereof.

Claim 2. (Cancelled).

Claim 3. (Original): A composition according to claim 1 wherein the pharmaceutically acceptable salt of L-ascorbic acid is sodium ascorbate.

Claim 4. (Original): A composition according to claim 1 wherein the pectin is a citrus pectin.

Claim 5. (Original): A composition according to claim 1 wherein the pectin is present in the composition at about 0.5% to about 5% by weight, calculated based on the total weight of the composition.

Claim 6. (Original): A composition according to claim 5 wherein the pectin is present in the composition at about 0.5% to about 2% by weight, calculated based on the total weight of the composition.

Claim 7. (Currently amended): A composition according to claim 1 wherein the composition consists of 95-99% by weight of L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and 1-5 [(5-1)]% by weight of pectin.

Claim 8. (Previously presented): A compressed tablet formed from a powder or granule composition consisting of:

Application No.: 09/738,610
Amendment Dated: August 4, 2004
Reply to Advisory Action Dated: July 26, 2004

- (a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof;
- (b) a binder consisting of about 0.1 to about 10% by weight of pectin, based on the total weight of the composition; and
- (c) a lubricant or mixture of lubricants.

Claim 9. (Cancelled).

Claim 10. (Previously presented): A compressed tablet according to claim 8 wherein the lubricant or a mixture of lubricants are selected from the group consisting of stearic acid, a magnesium salt of stearic acid, a calcium salt of stearic acid, and glyceryl behenate 45 (Compritol 888 ATO).

Claim 11. (Previously presented): A compressed tablet according to claim 8 wherein the lubricant or a mixture of lubricants is present in the tablet in an amount of about 0.5 to 4% by weight, calculated based on the total weight of the composition.

Claims 12-13. (Cancelled).

Claim 14. (Withdrawn): A process for preparing a powder or granule composition comprising:

- (a) forming a fluidized bed comprising fluidized particles of L-ascorbic acid and/or a pharmaceutically acceptable salt thereof; and
- (b) spraying from about 0.1 % to about 10% by weight of a pectin binder onto the fluidized particles of L-ascorbic acid.

Claim 15. (Withdrawn): A process according to claim 14 wherein the aqueous slurry has a solids content of about 10% to about 70% by weight.

Claim 16. (Withdrawn): A process according to claim 15 wherein the slurry has a solids content of about 25% to about 50% by weight.

Application No.: 09/738,810
Amendment Dated: August 4, 2004
Reply to Advisory Action Dated: July 26, 2004

Claim 17. (Withdrawn): A process for preparing a powder or granule composition comprising:

(a) forming a fluidized bed containing fluidized particles of L-ascorbic acid and/or a pharmaceutically acceptable salt thereof within a fluidized-bed drying device fitted with spray means, the fluidized bed being fluidized by air or an inert gas, and

(b) spraying an aqueous solution of pectin in the form of an atomized mist onto the fluidized particles to deposit pectin onto the fluidized particles.

Claim 18. (Withdrawn): A process according to claim 17 wherein the composition contains about 0.1% to about 10% by weight of pectin.

Claim 19. (Withdrawn): A method of binding a powder or granule composition comprising:

(a) forming a fluidized bed comprising fluidized particles of L-ascorbic acid and/or a pharmaceutically acceptable salt thereof; and

(b) spraying from about 0.1 % to about 10% by weight of a pectin binder onto the fluidized particles of L-ascorbic acid to bind the powder or granule composition formed.

Claim 20. (Withdrawn): A method of making a compressed tablet with improved color stability and tablet hardness comprising:

(a) forming a fluidized bed comprising fluidized particles of L-ascorbic acid and/or a pharmaceutically acceptable salt thereof; and

(b) spraying from about 0.1 % to about 10% by weight of a pectin binder onto the fluidized particles of L-ascorbic acid to form a powder or granule composition; and

(c) forming a compressed tablet from the powder or granule composition.

Application No.: 09/738,610

Amendment Dated: August 4, 2004

Reply to Advisory Action Dated: July 26, 2004

Claim 21. (Withdrawn): A method of binding L-ascorbic acid and/or a pharmaceutically acceptable salt thereof comprising:

- (a) forming a fluidized bed comprising fluidized particles of L-ascorbic acid and/or a pharmaceutically acceptable salt thereof; and
- (b) spraying from about 0.1 % to about 10% by weight of a pectin binder onto the fluidized particles of L-ascorbic acid to form a powder or granule composition.

Claim 22. (Currently amended): A powder or granule for making tablets consisting of comprising:

- (a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof, and
- (b) about 0.1 to about 10% by weight of pectin binder, calculated based on the total weight of the composition thereof, the composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder.

Claim 23. (Currently amended): A powder or granule for making tablets consisting of:

- (a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof,
- (b) about 0.1 to about 10% by weight of pectin binder, calculated based on the total weight of the composition thereof, and
- (c) A composition according to claim 22 further comprising about 0.1 to 10% by weight of an adjuvant and/or an excipient selected from the group consisting of dextrinized sucrose (Di Pac Sugar), microcrystalline cellulose, starch, and mixtures thereof calculated based on the total weight of the composition,
the composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder.

Application No.: 09/738,610

Amendment Dated: August 4, 2004

Reply to Advisory Action Dated: July 26, 2004

Claim 24. (Previously presented): A composition according to claim 22 wherein the pharmaceutically acceptable salt of L-ascorbic acid is sodium ascorbate.

Claim 25. (Previously presented): A composition according to claim 22 wherein the pectin is a citrus pectin.

Claim 26. (Previously added): A composition according to claim 22 wherein the pectin is present in the composition at about 0.5% to about 5% by weight, calculated based on the total weight of the composition.

Claim 27. (Previously presented): A composition according to claim 26 wherein the pectin is present in the composition at about 0.5% to about 2% by weight, calculated based on the total weight of the composition.

Claim 28. (Currently amended): A composition according to claim 22 wherein the composition consists of 95-99% by weight of L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and 1-5 ~~[[5-1]]~~% by weight of pectin.

Claim 29. (Currently amended): A compressed tablet formed from a powder or granule composition consisting of ~~comprising~~:

- (a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof, and
 - (b) about 0.1 to about 10% by weight of pectin binder, based on the total weight of the composition,
- the composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder.

Claim 30. (Currently amended): A compressed tablet formed from a powder or granule composition consisting of:

- (a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof.

Application No.: 09/738,610

Amendment Dated: August 4, 2004

Reply to Advisory Action Dated: July 26, 2004

(b) about 0.1 to about 10% by weight of pectin binder, based on the total weight of the composition,

(c) according to claim 20 further comprising a lubricant or a mixture of lubricants selected from the group consisting of stearic acid, a magnesium salt of stearic acid, a calcium salt of stearic acid, glyceryl behenate 45 (Compritol 888 ATO), and mixtures thereof, and

(d) an excipient selected from the group consisting of dextrinized sucrose (Di Pac Sugar), microcrystalline cellulose, starch, and mixtures thereof, the composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder.

Claim 31. (Canceled).

Claim 32. (Previously presented): A compressed tablet according to claim 30 wherein the lubricant or a mixture of lubricants is present in the tablet in an amount of about 0.5 to 4% by weight, calculated based on the total weight of the composition.

Claim 33. A compressed tablet formed from a powder or granule composition consisting of:

(a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof,

(b) about 0.1 to about 10% by weight of pectin binder, based on the total weight of the composition, and

(c) according to claim 20 further comprising an excipient selected from the group consisting of dextrinized sucrose (Di Pac Sugar), microcrystalline cellulose, starch, and mixtures thereof, the composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder.

Claim 34. (Canceled).